BY ORDER OF THE COMMANDER
AIR FORCE RESEARCH LABORATORY

AIR FORCE RESEARCH LABORATORY
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AFRL TEST ACTIVITY INVOLVING HUMAN PARTICIPANTS

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This publication implements AFRL Instruction 61-103, *AFRL Research Test Management*. This instruction provides guidance for review and approval of test activity involving human participants. This AFRL Instruction pertains to all AFRL test activities that involve human participants. The intent of this instruction is to ensure Air Force Research Laboratory researchers and organizations conducting test activity include appropriate reviews and documentation, assuring that risk to the human participant is minimized. In the event the activity constitutes human subject research such activity is referred for proper further review as defined by AFRLI 40-402, *Protection of Human Subjects in Research.* All applicable civilian personnel policies, instructions, and bargaining agreements will apply. This publication may be supplemented at any level, but all direct Supplements must be routed to the OPR of this publication for coordination prior to certification and approval. Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with (IAW) AFMAN 33-363, Management of records, and disposed of in accordance with Air Force Records Information Management Systems (AFRIMS) Records Disposition Schedule (RDS). Refer recommended changes and questions about this publication to the Office of Primary Responsibility (OPR) using the AF Form 847, *Recommendation for Change of Publication*; route AF Form 847 from the field through the appropriate functional manager's chain of command.

1. Purpose and Scope.

1.1. Purpose. The purpose of this instruction is to provide safeguards to enhance human participant safety in the conduct of research test activities. Approval to proceed with any test activity will be provided to the program manager (PM) by the designated test approval authority (TAA) IAW AFRLI 61-103, *AFRL Research Test Management*. This instruction

will provide guidance for obtaining reviews, as well as instruction for the conduct of those reviews.

1.2. Scope. The guidance contained in this instruction applies to all AFRL test activities involving human participants, including experiments and demonstrations that involve AFRL assets (full or part ownership) or AFRL personnel (government, military, and contractors), or where AFRL either holds mishap accountability or some level of liability. This guidance also applies to all tests executed by organizations under contract to AFRL where AFRL holds either mishap accountability or some level of liability.

1.2.1. Test activities involving human participants are defined as those activities which involve an interaction or intervention with an individual. For example, an intervention can involve physical procedures or a manipulation of the subject's environment. An interaction can include such activities as medical procedures, psychological testing, surveys, interviews, and focus groups.

1.3. Waivers. Coordinate waiver requests with local technology directorate (TD) test leads for coordination/staffing to the 711 HPW Technology Integration Branch (711 HPW/XPT). The 711 HPW/XPT will in turn coordinate waivers with AFRL Plans and Programs (AFRL/XP) and AFRL Safety Office (AFRL/SE) as required.

2. Roles and Responsibilities.

2.1. AFRL Detachment System Safety Personnel will:

2.1.1. Assist the PM in developing the safety component of the test plan and help determine if the activity constitutes human participants or human subject research. The Human Subject and Exemption Worksheet (Attachment 2) should be used to aid in making this determination. If the activity does constitute human subject research, it must be reviewed by the AFRL Institutional Review Board (IRB) (see AFRLI 40-402). If in doubt, refer the matter to the AFRL IRB for further official and final determination.

2.1.2. Undergo annual research reviewer training provided by the AFRL IRB. Such training will equip the trainee with the knowledge needed to assess whether or not a test plan constitutes test activity involving human participants or human subject research.

2.2. Program Manager (PM) will:

2.2.1. Contact the AFRL Detachment Safety Office and Directorate Test Lead early in the program development and activity planning stage and provide information concerning test requirements. The Program Manager is responsible for developing a test plan and coordinating that plan with the AFRL Detachment Safety Office and Directorate Test Lead.

2.2.2. Ensure timely compliance with all applicable requirements and be solely responsible for the planning and execution of the test activity. The Program Manager plans, conducts, manages and documents the activity in accordance with AFRLSUP 1/AFI 91-202, Chapter 13; AFRLI 61-103; and with this instruction.

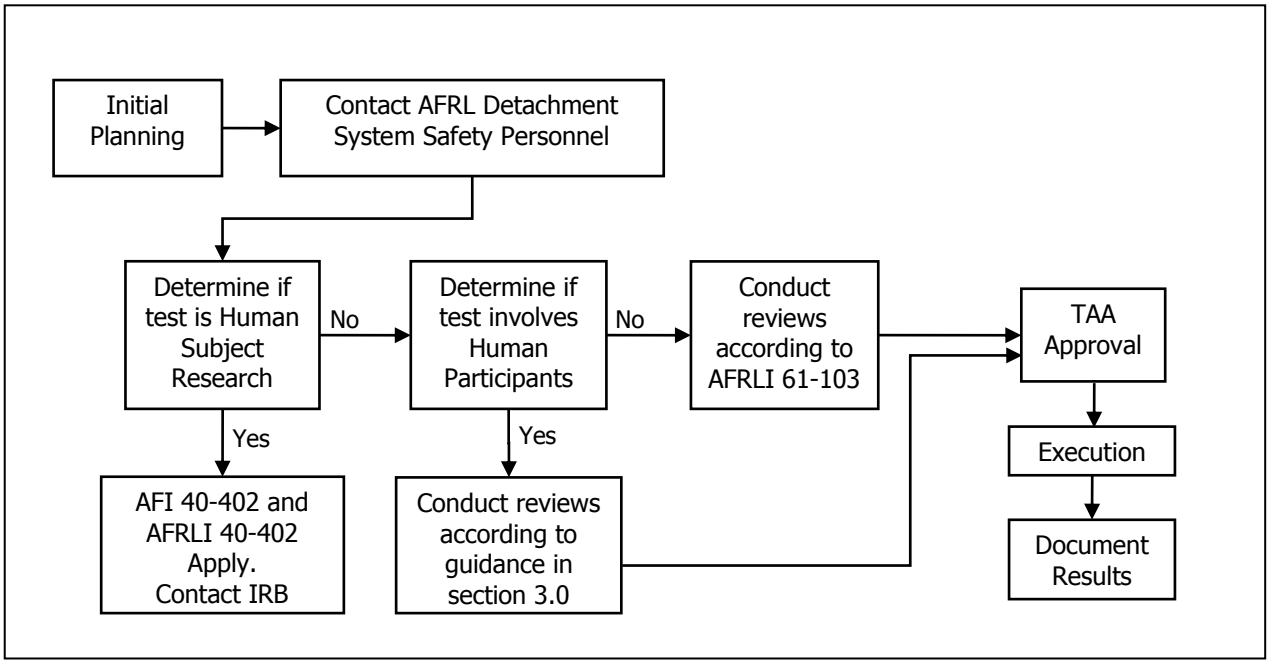
2.2.3. Keep the completed Human Subject and Exemption Worksheet (Attachment 2) as part of the case file.

3. Test Process.

3.1. AFRL Research Test Activity. All AFRL research test activity which potentially involves human participants will follow the determination and review process as depicted in Figure 1. When test activities include human participants, items related to their participation must be listed in the test plan as described Attachment 3. All test plans must be coordinated with the appropriate AFRL Detachment Safety Office prior to conducting any tests with human participants.

3.2. Testing. The test should be conducted in such a way as to avoid any mental or physical harm or unnecessary discomfort to participants. The test plan must detail the safety aspects taken into account for the test. During the course of the test, the PM, scientist, or engineer in charge must be prepared to terminate the test at any stage, if he or she has any cause to believe, in the exercise of good faith, superior skill and careful judgment that continuation of the test is likely to result in injury, disability, or death to the participant, or is unlikely to produce the expected outcome through technical, Operational Risk Management (ORM), safety, or other analysis method. No individual under the age of 18 will be a test participant.

Figure 1. Research Test Management Process for Human Participants



THOMAS J. MASIELLO, Major General, USAF
Commander

Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

Title 32 Code of Federal Regulations, Part 219, *Protection of Human Subjects,* current edition

DoD Directive 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,* 24 Apr 2007

DoD Directive 5000.2, *Operation of the Defense Acquisition System,* 12 May 2003

AFI 40-402, *Protection of Human Subjects in Biomedical and Behavioral Research,* 5 May 2005

AFI 91-202, *US Air Force Mishap Prevention Program*, 1 Aug 1998

AFMAN 33-363, *Management of Records,* 01 Mar 2008

AFRLI 40-402, *Using Human Subjects in Research*, 17 Oct 2008

AFRLI 61-103, *AFRL Research Test Management,* 1 Nov 2007

Adopted Forms

AF Form 847, *Recommendation for Change of Publication,* 22 September, 2009

Abbreviations and Acronyms

AFRL IRB (711 HPW/IR)—Air Force Research Laboratory Institutional Review Board

CFR—Code of Federal Regulation

ORM—Operational Risk Management

PM—Program Manager

RDT&E—Research, Development, Test and Evaluation

TAA—Test Approval Authority

TD—Technology Directorate

Terms

Generalizable Knowledge—New information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.

Human Subject Research—A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, when there is intervention or interaction with a human as the subject of the research. (For further discussion, guidance, and related terminology see AFI 40-402, *Protection of Human Subjects in Biomedical and Behavioral Research*, and AFRLI 40-402, *Protection of Human Subjects in Research).*

Human Subject—A living individual about whom an investigator conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable Private Information.

(For further discussion, guidance, and related terminology see AFI 40—402, *Protection of Human Subjects in Biomedical and Behavioral Research*, and AFRLI 40-402, *Protection of Human Subjects in Research*).

Human Participant—A living individual used to affect a test activity through intervention or interaction with the individual, but whom is not the subject of the activity. Focus data collected is not about the individual, but rather is about the object or design being tested.

Test Activity—For the purposes of this instruction, is an evaluation, demonstration, development, research, experiment, or other effort, which is non-systematic OR is not designed to develop or contribute to generalizable knowledge, (e.g., activity that does not meet the definition of Human Subject Research).

Test Activity Involving Human Participants—Any test activity that includes the use of humans through intervention or interaction and is NOT Human Subject Research. This typically applies in cases where the human being is not the focus of the test activity. For example, to use a human to evaluate the sound quality and physical comfort of a stereo headset, the human would not be the focus/subject of the test.

Attachment 2

HUMAN SUBJECT AND EXEMPTION WORKSHEET

Figure A2.1. Human Subject and Exemption Worksheet

Is it research?

_____1. The activity is a systematic investigation. For example, if the activity includes a hypothesis or clearly stated research question, utilizes research methodology, and has a plan for data analysis, then it is probably research.

_____2. The activity is designed to contribute to generalizable knowledge. Generalizable knowledge means new information that has relevance beyond the population or program from which it was collected, or information that is added to the scientific literature.

If yes to 1 and 2, it is research as defined by human research regulations. If no to either 1 or 2, it is not research and is not subject to human research regulations.

If a project has multiple components and at least one of those components is research, the entire project is classified as research unless the components are separable.

Are human subjects involved?

_____3. The activity involves collecting data about living people through an interaction or intervention with people. For example, an intervention can involve physical procedures or a manipulation of the subject's environment. An interaction can also include any of the following activities such as surveys, interviews, focus groups, psychological testing, or medical procedures.

_____4. The activity involves identifiable, private information. Private information is information provided for the specific purposes which the individual can reasonably expect will not be made public (e.g., medical, personnel, and student records), or information about behavior that occurs in a context in which the individual can reasonably expect no recording or observation is taking place. Identifiable information includes both direct identifiers and indirect identifiers. Direct identifiers include name, address, SSN, registration numbers, etc. Indirect identifiers include general demographic information when combinations of specific non-identifiable data can lead to individual identification (e.g., female, Marine officer, limited geographic area).

If yes to 3 **or** 4, the research involves human subjects and is within the purview of human research regulations. If no to both 3 **and** 4, then the activity is not subject to human research regulations.

Is the activity subject to human subject research regulations? (per this worksheet)

____Yes ____No ____Indeterminate/Not Sure

If the activity is identified as subject to human subject research regulations or "Indeterminate/Not Sure" per this worksheet, the project manager must ensure the activity is reviewed by the Air Force Research Laboratory Institutional Review Board (711 HPW/IR) IAW AFRLI 40-402.

For questions on this worksheet – POC: Lead IRB Administrator DSN 674-8094, Com (937) 904-8094.

Further information and documentation may be found at the following link
http://www.wpafb.af.mil/library/factsheets/factsheet.asp?id=7508

Attachment 3

ITEMS TO INCLUDE IN A TEST PLAN INVOLVING HUMAN PARTICIPANT IN TEST ACTIVITIES

NOTE: This outline contains many suggested topics to trigger your thoughts to cover all necessary topics. However, some may not be applicable to your specific program. Tailor the outline to fit your program.

Definition of Human Participant-A living individual used to affect a test activity through intervention or interaction with the individual, but whom is not the subject of the activity. Focus data collected is not about the individual, but rather is about the object or design being tested.

Figure A3.1. Items to Include in a Test Plan Involving Human Participant in Test Activities

A3.1. If living humans are required to participate in the test activity outside the role of the Program Manager, investigator, or investigative staff, of a test, the following items must be included in this section:¶

A3.1.1. Total number of participants¶

A3.1.2. Inclusion/exclusion criteria: screening, qualifications (skills) for participants ¶

and/or special tests required¶

A3.1.3. Identify participant's background (active/retired military, reserve, civilian)¶

A3.1.4. Age range of participants¶

A3.1.5. Risk factors and mitigation of risk efforts¶

A3.2. Describe in detail the role the human participants will play in the test. For example, what a participant will experience while taking part in the test. Summarize all pertinent information needed to follow the complete course of a test session and perform an adequate evaluation of the test design with regard to human participation. This section should lay out in detail how the participant will interact with test device or equipment, whether directly or indirectly.¶

A3.3. If any special skills are required of participants, the ability of participants to accomplish those skills must be evaluated prior to test participation (examples include swimming, sky diving, serving as a pilot, driving, etc.).¶

A3.4. Describe all possible hazards, risks and discomforts to participants to include both physical and psychological risks. For each identifiable risk, provide information on its incidence, the availability and effectiveness of treatment, and possible long-term or permanent effects. Include information on efforts taken to minimize any risks and maximize safety. Provide a comprehensive summary of all medical support requirements of the test program to include precautionary or preventative medicine measures required, if applicable.¶

A3.5. Specify any support required or any special safety precautions that need to be in place to ensure the protection of the human participant. If medical observers are needed, clearly state their qualifications, roles, and responsibilities.¶